IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT COOPERATION TREATY

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Applicants:	Chiron Corporation, et al.
Int'l Application No.	PCT/US03/06742
Int'l Filing Date:	03 March 2003 (03.03.2003)
Earliest Priority Date:	01 March 2002 (01.03.2002)
Title:	Methods and Compositions for the Treatment of Ischemia
Agent's File Reference:	19016.002 and CHIR-1-20669

RESPONSE TO WRITTEN OPINION

TO THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

ATTENTION: DONNA JAGOE, Authorized Officer/Examiner

In response to the preliminary Written Opinion mailed 12 April 2004, please enter the following:

REMARKS

In the preliminary Written Opinion, the International Preliminary Examining Authority has indicated that Claims 1-56 of the subject application lack novelty under PCT Article 33(2) as being variously anticipated by Sanofi-Synthelabo (EP 1,136,493 A1), Eldar-Finkelman (U.S. 2002/0147146 A1), Sanofi-Synthelabo (WO 01/70727 A1), and/or Nuss et al. (U.S. 2001/0044436 A1). The Examining Authority has relied upon Sanofi-Synthelabo 1 as teaching the administration of GSK3 inhibitors to treat cerebral vascular accidents, and supplementing the GSK3 inhibitors with an active ingredient of another medicament for the treatment of cerebral vascular accidents. The Examining Authority has relied upon Eldar-Finkelman as teaching the usefulness of GSK3 inhibitors for the treatment of biological conditions mediated by GSK-3 activity, such as conditions of ischemic insult, such as cerebral stroke. The Examining Authority has relied upon Sanofi-Synthelabo 2 as teaching the administration of GSK3 inhibitors to treat cerebral vascular accidents, and supplementing the GSK3 inhibitors with an active ingredient of another medicament for the treatment of cerebral vascular accidents. The Examining Authority has relied upon Nuss et al. as teaching the use of GSK3 inhibitors to treat brain injury and cerebral ischemia. These rejections are respectfully traversed.

Claim 1 of the subject application relates to the treatment of a human or animal subject by administering to the subject within 24 hours of the onset of an ischemic stroke event an amount of a glycogen synthase kinase 3 (GSK3) inhibitor effective to

reduce or prevent ischemic injury in the subject. Claim 2 limits the administration of the GSK3 inhibitor to within 8 hours of the onset of the ischemic stroke event. Claim 3 limits the administration of the GSK3 inhibitor to within 2 hours of the onset of the ischemic stroke event. None of the references cited by the International Preliminary Examining Authority disclose or remotely suggest the administration of a GSK3 inhibitor to a subject suffering from an ischemic stroke event within the time periods set forth in those claims. Accordingly, the references relied upon by the International Preliminary Examining Authority cannot anticipate the subject matter of those claims under PCT Article 33(2). Claims 2-16 all depend, directly or indirectly, from Claim 1 and similarly cannot be anticipated by these references. In addition, these claims contain further limitations that are not remotely disclosed or suggested by these references.

Independent Claim 17 of the subject application is directed to a method for treating cerebral vascular ischemic disorders by administering to a subject in need of such treatment an effective amount of a GSK3 inhibitor in combination with at least one additional agent for the treatment of ischemic stroke. Although the references relied upon by the International Preliminary Examining Authority broadly allude to supplementing GSK3 inhibitor therapy with another medicament for the treatment of the same disorder, none of the references disclose or suggest combination therapy with specific additional agents for the treatment of ischemic stroke. Accordingly, the subject matter of Claim 17 cannot be anticipated by these references under PCT Article 33(2). In addition, dependent Claims 18-20 further limit Claim 17 to administration of the GSK3 inhibitor prior to, concurrently with, or prior to and concurrently with administration of the at least one additional agent. The administration timing set forth in these claims is not disclosed or remotely suggested by any of the references relied upon by the International Preliminary Examining Authority. Similarly, dependent Claims 21-35 recite additional limitations not disclosed or remotely suggested by these references. Accordingly, Claims 17-35 cannot be anticipated by the cited references under PCT Article 33(2).

Independent composition Claim 36 and dependent composition Claims 37-47 recite specific compositions comprising a GSK3 inhibitor and at least one additional agent for the treatment of ischemic stroke. For the reasons set forth above in connection with Claims 17-35, composition Claims 36-47 are not anticipated by the references cited by the International Preliminary Examining Authority under PCT Article 33(2).

Method Claims 49-52 recite further limitations to the method of Claim 1. Method Claims 53-56 recite further limitations to the method of Claim 17. For the

reasons set forth above, the subject matter of these claims is not anticipated by the references cited by the International Preliminary Examining Authority.

CONCLUSION

For the reasons set forth above, Claims 1-56 of the subject application are not anticipated by the cited references. Reconsideration and a favorable international preliminary examination report is requested.

Respectfully submitted,

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30 April 2004

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